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RISK COMMUNICATION, MEDIA AMPLIFICATION AND THE ASPARTAME SCARE

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Abstract

On 14 July 2005, the Ramazzini Foundation held a press conference on the cancer risks posed by the sweetener aspartame, which received worldwide media attention. Scientists at the Ramazzini Foundation found that when administered to rats for their entire life span, aspartame, an artificial sweetener used in more than 6,000 food and pharmaceutical products, induces an increase in lymphomas and leukaemias in female rats. This study showed that aspartame causes cancer and was published online in the Foundation's in-house journal European Journal of Oncology. After a second publication on aspartame by the same institute, a number of scientists and European regulators started to question the validity of Ramazzini's findings. Events culminated following the publication of the European Food Safety Authority (EFSA) expert opinion on 5 May 2006 and the resulting press conference in Rome where the Authority announced that the Ramazzini study was problematic. It pointed out:

- *The slight increase in cancers known as lymphomas and leukaemias in the treated rats was considered to be unrelated to the aspartame treatment, and most likely attributed to the high background incidence of inflammatory changes in the lung.*
- *There was no dose–response relationship with respect to increasing doses of aspartame.*
- *With regard to the malignant tumours of the peripheral nerves, the numbers of tumours were low with no clear dose–response relationship over a wide dose range.*
- *The (cancer) findings in the kidney, ureter and bladder, observed mainly in female rats, were not specific to aspartame.*

This paper evaluates the communication and active social amplification of Ramazzini's research on aspartame, from the time of Ramazzini's initial press conference to the



time of EFSA's press conference, and is based on interviews with relevant regulators (most notably EFSA), scientists, stakeholders (industrialists, consumer representatives) and the media. The findings of the study note that the communication strategies used by the Ramazzini Foundation were not transparent, were focused on sensationalizing the results, were used to actively mislead the media and did not meet proper risk communication criteria.

Keywords

aspartame; risk communication; social amplification; media; Ramazzini; artificial sweeteners

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Background

Aspartame, a high intensity sweetener marketed under brands such as Equal, Nutrasweet and Canderel, was first discovered by the US-based company G.D. Searle in 1965. Because of possible cancer-related concerns, it was not approved for use in dry food products until the early 1980s and in soft drinks in 1983. Today aspartame remains a highly controversial sweetener. Many consumer groups take the view that it causes everything from cancer to hair loss, dementia and depression, that it is in the hands of industry groups, and that it has never been scientifically proven to be safe. As one of the opponents of aspartame, the UK Liberal Democrat MP Roger Williams noted:

The history of aspartame's approval is littered with examples showing that if key decision makers found against aspartame's safety, they were discredited or replaced by industry sympathisers, who were recompensed with lucrative jobs. (Williams, 2005)

Some opposed to the use of aspartame point out that the research on aspartame has been highly biased. In one review Walton points out:

Of the 90 non-industry-sponsored (independent) studies, 83 (92%) identified one or more problems with aspartame. Of the 74 aspartame industry sponsored studies, all 74 (100%) claimed that no problems were found with aspartame. (Walton, 1996)

Although assertions such as this one has been refuted by industry (e.g. Aspartame Information, 2007), over the years a whole anti-aspartame industry has blossomed, with the publication of books and self-help manuals on how to best avoid consuming aspartame (e.g. Hull, 1999; Mercola and Pearsall, 2006).

However, a number of government-sponsored scientific studies to date indicate that aspartame is not found unsafe (no evidence for harm) to consume as

an artificial sweetener (for a review see, e.g., US GAO, 1987; EU Scientific Committee on Food, 1985, 1989, 2002; AFSSA, 2002). In addition, industrialists and regulators point out that it has been used throughout the world for 30 years with no proven side effects (Aspartame Information, 2006).

Nevertheless, there are many news media risk-related trigger factors associated with aspartame. These trigger factors include the facts that

- Aspartame has had a mixed approval history (Food Magazine, 2006). The original four studies carried out for the Food and Drugs Administration were supposedly flawed (for an illuminating perspective see Cockburn, 2007). Research findings indicate that publics and stakeholders are concerned about such findings as it shows that the regulators may be incompetent, one of the key factors in determining public trust (Renn and Levine, 1991; Lofstedt, 2005).
- Aspartame is a popular sweetener found in many children drinks including crisps, Ribena, instant hot chocolate and jelly. The public is much more concerned about risks that may affect children than adults (Slovic, 1987, 2000).
- It is a widely used sweetener presently consumed by 200 million people worldwide (Lovett, 2006). Europeans alone consume 2,000 tonnes a year. In other words, there is a “scale” issue. Publics and regulators are much more worried about products/goods that can affect many individuals at the same time (Burgess, 2004).

In short, aspartame is controversial. Just one of these trigger factors would be enough to amplify any media story (Kasperson *et al.*, 1988; Pidgeon *et al.*, 2003), but all of them combined virtually guarantee front-page coverage in any tabloid newspaper.

Regulatory history of aspartame

Over the years there have been more than 200 scientific studies looking at whether aspartame is safe or not (e.g. Olney *et al.*, 1996; Soffritti *et al.*, 2006; Gallus *et al.*, 2007). Although a majority of the studies has indicated that aspartame is safe, ever since it came on the market there has been a scientific and stakeholder community that has questioned its safety. In the mid-1990s, for example, there were research findings indicating that increases in brain tumours and breast cancer could be linked to the sweetener (Olney *et al.*, 1996; Flamm, 1997; Gurney *et al.*, 1997; Koestner, 1997). These research findings were found to be incorrect when the occurrence of the various cancers occurred at the same time as the consumption of aspartame was increasing. As there is a significant time lag between dose and response, particularly with regard to cancers, such an increase in cancer should have happened much later in the exposed population (Lovett, 2006). The last overview study discussing possible risks associated with aspartame was conducted by the EU Scientific Committee on Food in 2002: it concluded that aspartame is safe (EU Scientific Committee on Food, 2002).

In 2005, however, the European Foundation of Oncology and Environmental Sciences, more commonly referred to as the Ramazzini Foundation, published initial findings of a study, stating that aspartame caused cancer in laboratory animals. Ramazzini, in the words of Dr Belpoggi, is

an independent, non-profit entity, dedicated to the prevention of cancer for more than 35 years. Its mission is the prevention of tumours via scientific research, the training of specialised personnel, and the diffusion of information on environmental and industrial carcinogenic risks...Projects of the Foundation are funded by grants from regional, national and international scientific institutions, public entities and private bank foundations. (Belpoggi, 2007, p 3)

The publication of the initial and subsequent Ramazzini studies took the world by storm as it was seen as a scientific “outlier”, questioning the commonly held scientific opinion. UK newspapers included headlines such as “Cancer linked to sweetener” and the uproar led a UK Liberal MP to propose a ban of the sweetener (Lawrence, 2005c).

Research objectives of the paper

This paper examines how the science findings surrounding the Ramazzini aspartame studies were communicated from the time of the initial press conference in July 2005 to EFSA’s press conference on the same studies in May 2006. In particular, it

- Examines how the scientific findings of Ramazzini were amplified by the media, and how the media stories in the mainly UK press changed from the time of the initial Ramazzini press conference on the first study to EFSA’s press conference a year later.
- Analyses the Ramazzini–EFSA interactions. How and why did Ramazzini react the way it did to EFSA’s repeated requests for the core data?
- Examines possible lessons for media in terms of how they can avoid being manipulated in actively amplifying scientific findings inappropriately.

Research methodology

For this article, the following research methodologies were used:

- A literature review of relevant food risk communication articles over the past five years.
- A review of aspartame-related research findings over the past 10 years with a specific focus on the last two years.
- Interviews with research and communication officers at a number of scientific and regulatory authorities most notably: DG SANCO, EFSA, Swedish Food Administration, UK Food Standards Authority (UK FSA), US Environmental Protection Agency (US EPA), US Food and Drug Administration (US FDA).

- Interviews with leading food journalists/correspondents at *Dagens Nyheter*, *Financial Times* and the *Wall Street Journal*.
- Interviews with regulatory and communication affairs personnel at Coca Cola Company and the International Sweeteners Association.
- A content analysis of UK-based newspapers from May 2005 to March 2007.
- A review of the “grey” literature on food-related policy issues put forward by EFSA and the UK FSA over the past four years.

Researchers at the Ramazzini Foundation were contacted on four separate occasions requesting an interview for this study. They refused to return e-mails and phone calls.

The Ramazzini Foundation

Researchers at the Ramazzini Foundation have long been interested in studying the link between chemicals and cancer. The Foundation’s research programme is concentrated in three particular areas, namely experimental carcinogenicity bioassays, experimental anticarcinogenesis assays and epidemiological studies. Its work on experimental carcinogenicity assays began in 1966. To date they have conducted more than 398 of these assays on 205 compounds using some 148,000 animals monitored until their spontaneous, or natural, death (Belpoggi, 2007). Of the compounds examined, 47 agents have shown clear evidence of carcinogenicity (Soffritti *et al.*, 2002c). The Foundation’s cancer research credentials were established when Professor Cesare Maltoni (first Director and then scientific director of the Ramazzini Foundation) uncovered a link between vinyl chloride and cancer in January 1973. At levels of 500 and 250ppm vinyl chloride caused the formation of tumours of the ear, kidney and liver in laboratory animals (Maltoni, 1974; Maltoni *et al.*, 1984, 1985; Badaracco, Jr 1985).

The research team at Ramazzini conducts research on:

agents that have been selected on the basis of the amount produced, their diffusion into the environment, and the number of people potentially exposed. Very few agents have been selected from those already proven to be carcinogenic in other laboratories. (Soffritti *et al.*, 2002c, p 28)

None of these later studies have been as well received as the one on vinyl chloride, and over time regulators and the scientific community have begun to question the Ramazzini Foundation’s scientific research and communication methods. They note, for example, that letting the laboratory animals live their natural deaths before conducting a pathology is an outdated research methodology. Killing the animals at a certain end point and then conducting a pathology produces less “noise” as it is considerably easier to determine whether a cancer was actually caused by the chemical being tested rather than by natural

causes (EFSA, 2006b; UK CC, 2006). Similarly, scientific bodies question whether the Ramazzini Foundation complies with Good Laboratory Practice (GLP), as there was no external quality control which GLP requires (UK CC, 2006). As EFSA points out:

Although there is a statement in the report that the study was conducted in accordance with GLP, it was confirmed that neither the ERF [Ramazzini] nor the study in question has been inspected by the Istituto Superiore di Sanita (the National Institute of Health, the Italian GLP compliance monitoring authority). The author's claim of GLP compliance of this study cannot, therefore, be confirmed at this stage... (EFSA, 2006b)

There have also been underlying concerns for a number of years that the animals in the facility have poor health caused by infections (UK CC, 2006). In response to these accusations, Professor Soffritti and his colleagues at the institute say that their experiments are conducted according to Italian law regulating the use and humane treatment of animals for scientific purposes (Soffritti *et al.*, 2007); that they have always used the same research methodology (spontaneous death); that their research findings do not differ significantly from 110-week studies (Huff, 2002; Belpoggi, 2007); and that their research has resulted in tightening public health regulations in certain instances in both Europe and North America (Soffritti *et al.*, 2002a,b; 2006; Soffritti, 2007). Finally, while Professor Soffritti acknowledges that the Institute's animals are not in an artificial sterile environment, he says that this is ideal as humans are also exposed to environmental elements (Soffritti, 2007).

The dissemination strategy used by the Ramazzini Foundation has also been questioned. The institute has published a majority of its findings in its own in-house journal (*European Journal of Oncology*) or in non-peer-reviewed journals such as the *Annals of the New York Academy of Sciences* rather than in properly scientific peer-reviewed journals. Similarly, the institute has a reputation for holding press conferences (without the data being published in peer-reviewed journals), withholding scientific data from regulators, and not actively participating in the scientific peer-review process (Lovett, 2006). In their defence, Soffritti and his colleagues point out that a number of their papers have been published in peer-reviewed journals such as *Environmental Health Perspectives* (Soffritti, 2006; 2007), the official journal of National Institute of Environmental Health Sciences (NIEHS), and that it has always been their policy to communicate first and publish later. As Belpoggi recently noted:

It is ERF (Ramazzini) policy to communicate and then to publish first results as soon as they are available. This origin of this policy dates to well known case of Marghera, Italy where producers of VCM were convicted for the

murder of factory workers. The defence initially used the argument that they learned of Maltoni's results only upon peer-reviewed publication in 1977 and were therefore incognizant of the dangers of VCM. In reality, these data were first presented in 1972 and Maltoni was asked to demonstrate that he had in fact communicated these results as soon as they were observed. (Belpoggi, 2007, p 12)

The artificial sweetener aspartame fit well within the Ramazzini Foundation's criteria for cancer analysis. It is a sweetener that is widely consumed. In addition, the aspartame study is more or less a continuation of the Institute's earlier methanol study. Aspartame is made up of two amino acids, with an extra group called a methyl ester attached to the phenylalanine portion. In the stomach this methyl ester becomes methanol, and as this is an unstable substance, the body converts it to formaldehyde, a product that research at the Ramazzini Foundation has shown to cause cancer in the past (Soffritti *et al.*, 1989). The aspartame study was completed in the summer of 2005 after eight years of research involving some 1,800 rats, generating 34,000 slides and costing approximately 1 million euros.

How were the scientific results communicated?

Once Soffritti and his colleagues completed their research on the aspartame-cancer link, they communicated their scientific results in a number of different ways. Firstly, prior to the initial results being published in their own in-house journal they gave a number of presentations (consisting of power point slides along with 30 colour photocopied slides of the cancers in question) of their preliminary results to regulators and universities. In April 2005 there was a presentation to the Italian Ministry of Health in Rome and at the end of June 2005 presentations were made to EFSA, the Herbert Irving Comprehensive Cancer Centre at Columbia University, the National Cancer Institute of the US Government and the National Toxicology Program of the US National Institutes of Health.

On 11 July 2005 it was announced that the Ramazzini Foundation would arrange a press conference at 11 am on 14 July 2005. Following this announcement EFSA prepared a press release in order to advise the public and interested parties immediately that EFSA was aware of the study and would undertake its evaluation following receipt of data. According to EFSA's usual practice, the press release was circulated under embargo to national food safety authorities, the European Commission and stakeholders most concerned by the announcement (in this case BEUC (European Bureau of Consumers' Association) and CIAA (European wide food industry association)). On the morning of 14 July, the International Sweeteners Association (ISA) contacted EFSA and asked them to stop their press release going ahead until it was known how important

the press conference would actually be. EFSA refused this request and issued its press release at 11 am on 14 July, just as the press conference started in Bologna, arguing that it needed to be as proactive as possible to allay any possible public fears regarding aspartame.

At its press conference, the Ramazzini Foundation noted that their initial findings were currently being published in their in-house journal, *European Journal of Oncology* (Soffritti *et al.*, 2005). This is a scientific journal but is not technically peer-reviewed, as any peer-review is done by the scientists within the centre themselves. The paper with “in press” was made available on the day of the press conference and was published on the Ramazzini website. The press conference attracted seven journalists from a number of different Italian newspapers. At this stage, interest in the press conference seemed to be confined to the Italian press with Soffritti appearing for three minutes on the local RAI3 channel; however, after a few hours the Italian National Press Agency (ANSA) picked up the story and within a very short time the story spread throughout the rest of the continent. Once the story went Europe-wide, the ISA sent statements to selected agencies and newspapers in Italy and elsewhere noting that aspartame does not cause cancer. Key UK media including BBC News Online (14 July 2005), the *Daily Mail* (15 July 2005), the *Guardian* (15 July 2005) and the *Daily Express* (19 July 2005) referred to the Ramazzini press conference and the ISA statement with headlines including *Daily Mail*’s “Sweetener’s link to cancer denied” (Poulter, 2005) and the *Guardian*’s “Fresh fears raised about aspartame: Manufacturers dispute study into lab rats fed sweetener” (Lawrence, 2005a). On 15 July all European food agencies received a personal statement from Herve Nordman, Chair of the Scientific and Regulatory Committee of the ISA, with the ISA statement as well as statements made by two Italian professors (Garattini and La Vecchia, both consultants to ISA) stating that there is no link between aspartame consumption and cancer. In the evening of 15 July, Garattini appeared on Italian television (RAI3) recommending caution regarding the Ramazzini data.

There were six key reasons as to why the Ramazzini study received so much initial media coverage:

- The trigger factors discussed earlier – newspaper journalists picked up phrases such as children and aspartame being mass produced.
- The contested regulatory history of aspartame.
- The Ramazzini Foundation’s press conference – most research groups do not hold a press conference following the publication of an article in their in-house journal.
- The science and political reputation of the Ramazzini Foundation – the institute has produced more than 200 cancer studies in the past 35 years and is known to be a cancer research organization. In addition Professor

Soffritti himself is seen as a media science guru appearing frequently on Italian television and radio, and the Institute has very good local and national political connections.

- The EFSA decision to publish a press release at the same time as the Ramazzini Foundation held its press conference, thereby signalling the possible international importance of the research findings (Renwick and Nordmann, 2007).
- The response from ISA – sending statements to selected agencies and newspapers noting that aspartame is a safe sweetener.

In September 2005 researchers at the Ramazzini Foundation presented their aspartame results at their own scientific conference in Bologna entitled “Framing the Future in Light of the Past: Living in a Chemical World” that was attended by academics from Europe and North America. The presentations the researchers gave at this conference were similar to the presentations they gave in June 2005 to the various regulatory and university bodies in Europe and North America. There were two press conferences held at the conference, but only three journalists attended each. The Acting Executive Director and Director of Science of EFSA, Dr Herman Koeter, gave a keynote on EFSA’s mission, before the roundtable session on the last day of the conference. He was asked when EFSA would make an evaluation of the Ramazzini Foundation results. He replied that this would be done once EFSA received the required scientific data. Newspaper articles arising from the press conferences were fairly limited. The *Guardian* carried one piece on 30 September reporting that researchers presented new research in Bologna which sweetener manufacturers disputed (Lawrence, 2005b).

On 17 November 2005 the Ramazzini Foundation issued a press release announcing that its final paper on the aspartame–cancer link had been published online in the peer-reviewed journal *Environmental Health Perspectives*. The institute reissued this press release on 1 March 2006 once the paper had been published in print. There was a delayed reaction to this press release. A number of articles appeared in the Belgian and Dutch press and there was coverage in the journal *EU Food Law*.

During this period EFSA was urgently trying to begin its risk assessment on aspartame using primary data from the Ramazzini Foundation. EFSA initially requested this information in June following the presentations made by the Ramazzini researchers to EFSA, and Dr Herman Koeter requested it again when he attended the institute’s September symposium. In addition, Dr Koeter called the Ramazzini Foundation a couple of times in the autumn of 2005 requesting for the data, but it was still not forthcoming. To put more pressure on the Ramazzini Foundation, the EFSA unprecedentedly issued a press release on 29 November urging the institute to send the Agency these data (EFSA, 2005a). On 15 December the Ramazzini Foundation confirmed verbally that

the Italian Ministry of Health and the EFSA would receive the full 900-page report with some of the scientific data. On 16 December Ramazzini invites EFSA to pick up the data from their premises in Bentivoglio, Bologna. On 19 December, EFSA acknowledged that it had now received these scientific data and it would give high priority to its scientific risk assessment (EFSA, 2005b). Crucially, however, the report did not contain any of the 34,000 slides that the Institute had made during the toxicological study. When Dr Koeter and scientists across the world asked for these data from Ramazzini the official response was

...we do not think it is appropriate for slides to be reviewed on data that has already been published. It's 34,000 slides and eight years work. Dr Soffritti is not open to a third party reading a small subset of slides and issuing an opinion on the study. (Kathryn Knowles, quoted in Lovett, 2006)

In mid-December 2005 the aspartame controversy took on a political dimension. The UK Liberal MP, Roger Williams, held an adjournment debate in the House of Commons on aspartame concluding that the substance should be banned similarly to the removal of food stuffs containing red food dye Sudan 1 for legal reasons, citing the Ramazzini Foundation's study as the new "monumental" study that should have "set alarm bells ringing in health departments around the world" (Williams, 2005):

There is compelling and reliable evidence for this carcinogenic substance to be banned from the UK food and drinks market. (Williams, 2005)

The Public Health Minister Caroline Flint responded to these allegations in the House of Commons by noting that she took the issue very seriously and would look at new data but noted that the UK expert Committee on Carcinogenicity had reviewed Ramazzini Foundation's research on aspartame and had not been convinced by its interpretations (Flint, 2005).

The adjournment debate led to immediate articles in the UK press. An article on the front page of the *Daily Express* had the headline: "Cancer is linked to sweetener – Risk in 6000 food and drink products" and quoted both Roger Williams and the Italian (Ramazzini) study. On page 7 of the *Guardian* on the same day the headline ran: "Safety of artificial sweetener called into question by MP". These strongly worded headlines lead to public concern as to whether they should be eating food containing aspartame. The *Daily Express*, for example, stated that the day after its front-page article, it was bombarded with calls from readers worried about the artificial sweetener (Price, 2005). There were also a number of follow-on articles in the UK press. For example, the *Daily Express* ran an article on 17 December with the headline "Crippled girl walks again after giving up sweetener".

In the period from January to May 2006 Ramazzini's two scientific papers were in the public domain, but journalists, scientists and other stakeholders were waiting for the EFSA opinion on the research. In the first two months alone, EFSA's communication department received approximately 20 phone calls from journalists wanting to know when the opinion would be out. In addition, EFSA was trying to get hold of more scientific data from Ramazzini, but this was not forthcoming. On 31 January 2006, scientists at Ramazzini visited EFSA in Parma to discuss the aspartame findings in more detail, but the requested data were not provided. On 28 February, EFSA sent Ramazzini a reminder letter for the data promised, and a further reminder letter was sent on 24 March 2006. Finally, on 30 March Ramazzini sent EFSA a letter stating that more data would be available. On 19 April, Ramazzini notified EFSA saying that a CD rom was now available with further data. EFSA researchers travelled to Bentivoglio, Bologna that day to collect the file by hand. The file contained, among other information, the individual rodent data in a 2,400-page plus report, but crucially none of the original 34,000 slides. On the same day that EFSA collected this CD Rom, Ramazzini sent the same file to the Italian and US authorities.

During this time, one influential article was published in the *New York Times* (12 February). The front-page article under the title "New research, new fears about a sweetener's risks" focused on Soffritti's study showing an aspartame-cancer link, and the 30+ years of controversy surrounding the sweetener, and concluded with a quote from Michael Jacobson, executive director of the Centre for Science in the Public Interest:

For a chemical that is used by hundreds of millions of people around the world, it should be absolutely safe. There should be no doubt. (Jacobson in Warner, 2006)

The *New York Times* article by Melanie Warner was syndicated by a number of newspapers including the *Daily Telegraph* and the *International Herald Tribune*. In a follow-up piece, the *New York Times* ran an editorial on 21 February questioning the safety of aspartame (NYT, 2006).

In the last week of April 2006, Dr Koeter visited Professor Soffritti and informed him that the conclusions that EFSA had come to would be constructively critical of the Institute's work. He invited Professor Soffritti to attend the forthcoming press conference and say a few words afterwards.

On 5 May 2006, EFSA held a press conference in Rome summarizing its scientific opinion of the aspartame report and put the full report on its website. The press conference was attended by 21 journalists, with interpretation into three languages (German, French, Italian) and was also web cast with some 998 live viewers (and 2,200 viewers by 19 September 2006). The EFSA panel concluded that a number of cancers were irrelevant (kidney, ureter and

bladder) as they were specific to rats and not humans; and the “slight increase in cancer known as lymphomas and leukemias in treated rats was considered to be unrelated to aspartame treatment and most likely attributed to the high background of inflammatory changes in the lung....The panel concluded that based on all of the available data to date there is no reason to further review the previous scientific opinion on the safety of aspartame...” (EFSA, 2006a). Following the press conference Professor Soffritti was asked his views and he said:

I have told them (children/grandchildren) to shun medicine, syrups, antibiotics, sweets and other products with aspartame. The results showed that female rats had increased leukemia and lymphoma rates. That is why we do not recommend it for pregnant women or children and why we have commissioned a new study. (Soffritti in Macfarlane, 2006)

Similarly a press release on Ramazzini’s website just after the EFSA press conference notes:

Because of the globalisation of the industrialised diet and the ever increasing use of artificial sweeteners among billions of people in both industrialised and developing countries, the European Ramazzini Foundation considers its work on sweeteners to be of the highest priority for the protection of public health, in particular the health of children and pregnant women who are among the most vulnerable populations. (Ramazzini Foundation, 2006)

EFSA press conference received significant press coverage. A *Daily Mail* page 13 headline ran: “Sweetener cleared from cancer link”. The *Times* reported: “Sweetener is not a cancer risk”, the *Daily Express* said: “Experts in cancer U-turn”, and Reuters noted “EU food body dismisses food sweetener cancer fears”.

Following the press conference, Professor Soffritti and his colleagues attacked EFSA’s opinion. In August 2006 he said in a letter to *Environmental Health Perspectives* that EFSA’s conclusions were bizarre, because if the lymphomas/leukaemias observed were indeed caused by an infected colony, then one would observe these cancers not only in females, but also in males. Similarly he noted that the same scientific scrutiny that EFSA applied to his studies has not been applied to the April NCI diet questionnaire survey (Lim *et al.*, 2006). He questioned whether aspartame is an early- or late-stage carcinogen noting that this needs to be researched (Soffritti, 2006).

In the period August 2006 to June 2007, the supposed aspartame–cancer link has remained in the news. The main reason why it has not gone away is due to yet another Ramazzini aspartame study showing a lab rat–cancer link. The researchers at Ramazzini were able to keep the topic newsworthy by

holding a press conference on their new then unpublished findings in April 2007 at New York's Mt Sinai School of Medicine at the occasion of presenting Professor Soffritti with the Irving J. Selikoff Award, a prize funded by the Ramazzini Foundation itself. This press conference was widely covered by the US media. At the time of the press conference, the FDA refuted the Ramazzini claims and put out a statement that aspartame is safe for human consumption (FDA, 2007a). In June 2007, the results of the second aspartame study was accepted for publication in *Environmental Health Perspectives* (Soffritti *et al.*, 2007), and shortly after US consumer groups encouraged Americans to avoid aspartame-containing products (Fox, 2007). This was also echoed by Soffritti and colleagues when they noted:

On the basis of the present findings, we believe that a review of the current regulations governing the use of aspartame cannot be delayed...This review is particularly urgent with regard to aspartame-containing beverages, heavily consumed by children. (Soffritti *et al.*, 2007)

As before the Ramazzini Foundation refused to share slides of their latest research findings with authorities in North America or Europe.

Analysis of the risk and media amplification surrounding aspartame

In conducting an evaluation of how Ramazzini's research findings were communicated and amplified, a number of features stand out: the research-media link, the development of an information vacuum creating and enhancing ripple effects, the lack of transparency, and "sloppy" reporting by the media. These issues are discussed below.

The research-media link

The Ramazzini Foundation used the media frequently and effectively. In the period from June 2005 to May 2006 it held no less than five press conferences and issued multiple press releases regarding its aspartame study. Clearly the Foundation felt comfortable in reporting its results through the media, appearing to actively and repeatedly try to court media attention in a way that most research institutions would not do (for a discussion see Friedman *et al.*, 1999). Rather these institutions would share their results with their colleagues at international research meetings and with regulators. Indeed, because of the Ramazzini Foundation's strong media focus, sweetener manufacturers accused the researchers at Ramazzini of "criminal" behaviour in presenting data publicly before it had been made available to regulatory authorities (Lawrence, 2005b).

There are several possible reasons for such behaviour: the institute is dependent on "soft money" and therefore has to ensure that as many potential

fundings as possible know about the research it conducts. In other words, the greater publicity the institute generates the more famous it becomes and the more funding it receives. In addition, publishing research findings it knows will be amplified by the media, puts pressure on politicians to react (as shown by Roger Williams MP and his call to ban aspartame) to its findings. Finally, as Belpoggi noted, the Ramazzini Foundation has a policy to communicate first and publish later to ensure that regulators, media and industry are aware of the findings before they are published (Belpoggi, 2007).

There is one main problem associated with this research-media communication strategy. Journalists do not generally distinguish between non-peer-review and real peer-review, as noted by previous research (e.g. Atkin and Wallack, 1990; Friedman *et al.*, 1999; Hargreaves *et al.*, 2003; Social Issues Research Centre and the Amsterdam School of Communications Research, 2006). As a result, although the aspartame research findings were initially speculative and published in an in-house journal, they were reported as more or less state-of-the-art peer-review science. The Ramazzini study may thus have received more credence than warranted.

The creation of an information vacuum

Between the publication of the Ramazzini Foundation's initial results in July 2005 and that of the EFSA opinion in May 2006 – a period of almost 10 months – an information vacuum existed. Regulators and researchers did not know whether the Ramazzini Foundation studies were either accurate or whether the foundation's findings were relevant to humans. Was there a link between aspartame and cancer? The media wanted answers to this question and did not receive them as the EFSA did not have them. In terms of communicating science, information vacuums are dangerous. If there is no absolute certainty regarding a risk topic, some research groups, politicians, stakeholders and others will add their views to the debate, which in turn will more often than not be picked up by the media (Powell and Leiss, 1997; Leiss, 2001). This is exactly what happened here.

As there were no scientifically verified facts on the table, politicians like Roger Williams were able to politicize scientific uncertainty to promote their own political position. By stating that he wanted to ban aspartame, he was virtually guaranteed media attention, due to the trigger factors discussed earlier and, more notably, because the UK had already experienced a number of food scares ranging from mad cow disease, to GMOs to foot-and-mouth disease (Gaskell *et al.*, 1998, 2000, 2004), resulting in public distrust of the regulator (Lofstedt, 2005, 2006). To complicate matters still further, his call to ban aspartame came just after the UK FSA had decided to seek withdrawal from sale substances containing the red food dye Sudan 1, citing legal reasons (see Hutton and Wadge, 2006). If products containing Sudan 1 could be withdrawn for simple legal reasons, then why could not aspartame be banned when

it supposedly caused cancer? Similarly, as aspartame is such a controversial product, individuals opposed to it for one reason or another were able to promote their cause, citing the new and influential Ramazzini study (Hull, 2006; Mercola and Pearsall, 2006; Warner, 2006).

There is no “perfect” way for researchers to communicate with regulators. But it is current scientific best practice for important carcinogenicity studies to undergo peer-review of the pathology slides, as is the case, for example, for studies conducted by the US National Toxicology Programme. Similarly if studies are conducted in commercial laboratories under GLP, then national GLP authorities can gain access to slides for peer-review if they so wish (EFSA, 2006c). Finally, Section 8E of the US Toxic Substances Control Act (TSCA) requires a corporation that finds its chemical may cause something new (e.g. a lesion not seen before) in any test system (including *in vitro*) to report the finding within 30 days to the US EPA. It does not matter if the lesion is relevant to humans or not. If the corporation in question does not do this within the 30-day time limit, it will be fined more than \$25,000 each day until it files the scientific research findings. Because of Section 8E most companies err on the side of caution, releasing their data rather than not doing so.

An information vacuum that continues for almost a year long is a long time. Why did the Ramazzini researchers not share the scientific data, when they were clearly aware that the aspartame–cancer link would be amplified by the media? While the Ramazzini researchers were not required to inform the regulators of their findings, this is common and best practice. Researchers and regulators felt that the Ramazzini Foundation was no longer playing by the rules (Lovett, 2006).

The institute in its defence said that around 70 of the 34,000 microscope slides the researchers produced for the aspartame study were reviewed by scientists at the NIEHS National Toxicological Program (NTP), so in effect there was a form of miniature peer-review (Lovett, 2006). However, the NTP questioned the accuracy of a large number of Ramazzini’s interpretations (Hailey, 2004). In addition, the Ramazzini team said that EFSA and other scientific authorities had not subjected previous aspartame cancer studies (such as those carried out in the 1970s for Searle) to the same level of scrutiny as theirs (Soffritti, 2006). But other scientists pointed out that the Ramazzini study was an outlier (Lovett, 2006). Outliers, by their very nature, will receive much more scientific scrutiny than research findings confirming the *status quo*. Had the Ramazzini study been proven scientifically defensible, it would have been a tremendous scientific breakthrough leading to the probable ban of aspartame as a sweetener.

The delay in sharing the raw data with EFSA and other scientific authorities, created friction between the institute and the authorities. EFSA could not properly react to the findings as they did not have enough scientific information. This also affected industrialists, as their products were becoming increasingly

stigmatized (as cancer causing) while they lacked the scientific data to challenge the study. As a result of the Ramazzini Foundation withholding its aspartame data, regulators and academic scientists began to question its credibility. Had they been proud of their findings in the first place, some scientists have argued, then the researchers would have shared them with the wider research community and published them in leading peer-review journals, rather than actively pursuing media attention using press conferences (Lovett, 2006).

Creating and enhancing ripple effects

The aspartame case had a series of multiple trigger factors all more or less created by the researchers at the Ramazzini Foundation. The direct trigger factors in the time period July 2005–May 2006 were as follows:

- The 14 July 2005 press conference and resulting publication in the in-house journal.
- The September 2005 conference Framing the Future in Light of the Past: Living in a Chemical World.
- The publication of the final results of the findings in EHP.

Each of these trigger factors led to articles being published in the media in both Europe and North America: aspartame by its very nature is a socially amplified and amplifiable topic (Kasperson *et al.*, 1988; Pidgeon *et al.*, 2003). The social amplification model predicts that initial trigger factors will have ripple effects leading to secondary trigger factors. This is also what happened in the case of aspartame – the debate led by Roger Williams MP in the House of Commons was a direct result of the Ramazzini Foundation press conferences and press releases. His comments led to further ripples in the form of articles in the UK press. Similarly the February 2006 article in the *New York Times*, and the resulting syndication and follow-up editorial, is a tertiary trigger following from the Ramazzini Foundation press conferences. However, these ripple effects were amplified by the information vacuum. Arguably, had Roger Williams MP made his scientific statements in the House of Commons today, the media would have paid much less attention, as EFSA so strongly refuted the Ramazzini results. Similarly had the *New York Times* article been published today, it would also have received less further media attention. The journalist from the *New York Times* called the EFSA prior to the Authority having any insights to the Ramazzini study asking the scientists' opinions about the study. EFSA did not have the review of Ramazzini completed at the time, resulting in the story going to press without EFSA refutation. The information vacuum, itself enhanced by the ripple effects, therefore allowed news of the Ramazzini research to spread unchallenged still further and prolonged the aspartame controversy, arguably unnecessarily.

Lack of transparency

The 2005–2006 aspartame controversy was also plagued with a high degree of unnecessary secrecy. In many cases primary research is done behind close doors, but once it is published it becomes public knowledge. This means not only that scientific results are made available for public consumption (often by scientific editors in the media), but also researchers are transparent with regard to possible conflicts of interest and how the research was funded (for an excellent discussion see Horton, 2004). The aspartame scare is murky in both these areas. Unanswered questions concerning the Ramazzini Foundation's research findings include:

- Why were the initial scientific findings not properly peer-reviewed? Why did the Ramazzini research group publish its initial findings in an in-house journal, the *Journal of European Oncology*, rather than in a properly peer-reviewed journal?
- Why not share the 34,000 slides? A number of critics of the Ramazzini Foundation argued that if the research was as good as the research group says it is, it would be proud of its slides and share them with other researchers and regulators. This failure has led critics to conclude that their research was not properly conducted (Lovett, 2006).
- Who funded the study? The research project cost – according to Ramazzini's own estimates – 1 million euros. Unsubstantiated speculations about who funded it range from US trial lawyers to anti-soft drinks radicals to the sugar industry itself paying some of the costs associated with the project. The Ramazzini researchers say that they are a not-for-profit foundation and that they receive funding from a variety of sources including private individuals and that there are no conflicts of interest. This still does not answer the question: if these individuals funded the project, in the name of transparency it would be useful to have these individuals made public so the readers themselves can decide whether or not there is a conflict of interest.

Some serious questions have been raised. The official view from the Ramazzini Foundation is that they do not need to share their results with anyone – why should their findings be subject to excess scrutiny when the original findings were not? In addition, they argue that their in-house journal is a properly peer-reviewed journal and their paper in that journal was reviewed by seven eminent colleagues at Ramazzini. Finally, Professor Soffritti himself claims that he does share his results with scientific authorities and regulators. Following the EFSA press conference in May 2006 he noted:

International agencies like EFSA will continue to be our first point of reference and we will continue to keep them informed of our results in a timely manner as always. (Soffritti, quoted in Ramazzini press release May 2006)

This leads to a further problem. Ramazzini researchers appear to be using the scientific aura without adopting the basic norms that help to shape science (e.g. Popper, 1963; National Research Council, 1994). This is not unusual, however. More and more the so-called “scientific” research is being done outside academia, be it by think-tanks, stakeholders or industry, many not conforming to the adopted scientific norms (Nowotny *et al.*, 2001).

“Sloppy” journalism

One of the key components of this scare was the “sloppiness” of the journalists themselves reporting on the scare. There were many examples of this. On 15 December 2005, just after the debate led by the Liberal Democrat MP Roger Williams the *Daily Express* included the front-page headline “Cancer linked to sweetener”. The articles said that leading scientists joined forces with MPs to urge the Government to ban all products which contain aspartame. The article cited the Ramazzini study (Price and Guyoncourt, 2005). There are several problems with this article. Firstly the Ramazzini study by this stage was not new. The original study was published in July 2005 and the follow-up study was published in November 2005 on the internet. The only “expert” was Roger Williams MP, not an expert on aspartame *per se* but a politician and a farmer with a natural science BA degree from Cambridge. No other experts took part in the parliamentary debate, and no leading scientists participated in the debate, although two anti-aspartame scientists sat in the audience. To make matters worse the *Daily Express* was completely confused about the May 2006 EFSA announcement. It noted:

European food chiefs dismissed their own research which revealed health risks linked to the sugar substitute aspartame. In December, the *Daily Express* revealed that the European Safety Agency had linked aspartame ...to cancer in rats....The EFSA study was launched two years ago...Further EFSA research allegedly confirmed the Italian (Ramazzini) findings...”(Macfarlane, 2006, p 8)

In effect none of this reporting was accurate. The EFSA did not do an independent study on the aspartame–cancer link. It did not announce any results in December 2005 confirming the Ramazzini Foundation results. It did not refute its own findings in May 2006. Hence, a significant part of this article was a complete work of fiction.¹ In addition, on 6 May 2006, the *Daily Mail* reported on the 24-month study by EFSA (Pisa, 2006). In fact, the study was no more than five and a half months in duration. Similarly on the same day the *Times* ran a similar article regarding the EFSA findings, noting among other things that “this year” Roger Williams MP had asked the government to do something regarding the health risks posed by aspartame (Lister, 2006). Roger Williams had made this statement in December 2005.

Industry *vs* non-industry science

There is a common perception, particularly in the United States, that industry science is bad and that non-industry science is good (e.g. Lurie *et al.*, 2006). Increasingly, academics who have received funding from industry are no longer allowed to serve on regulatory scientific advisory boards as they are deemed to be too biased (e.g. FDA, 2007b; Lofstedt, 2007). This issue was frequently highlighted with regard to aspartame. As one anti-aspartame campaigner notes:

What we are witnessing as a result of the 2005 Italian study is a corporate panic to disengage public awareness of the truth. The marketers and manufacturers of aspartame are rallying in an effort to discredit the independent study's damaging results, and they are lobbying to resurrect their worn-out, payrolled corporate studies from 30 years ago to justify their claims of safety and resulting monopoly of the diet food industry. (Hull, 2006)

Or as Soffritti himself notes:

It is very important to have scientists who are independent and not funded by industry looking at this. (Soffritti quoted in Warner, 2006)

Similarly, Members of the European Parliament (MEP) questioned the credibility of the EFSA findings as two participants in the EFSA scientific review panel had previously had research funded by industry (Davies, 2006; EFSA, 2006c; European Food Law, 2006a, b, c, 2007), but did not question the credibility of the Ramazzini report or ask who funded it, something that Herman Koeter himself highlighted at the EFSA 2006 press conference (Lawrence, 2006). The Ramazzini Foundation too has previously received vast amounts of funding from industry, including for its first study on vinyl chloride (Badaracco, 1985). Maybe the Institute is therefore no longer credible? Such modern day "witch hunts" need to stop and scientific results be judged by how they stand up under scientific peer-review.

Risk communication

Over the past 30 years there has been much discussion about how risks should best be communicated. In 1989 the US National Research Council (NRC), in one of the definitive studies on risk communication, noted that:

"Risk communication is an interactive process of exchange of information and opinion among individuals, groups, and institutions. It involves multiple messages about the nature of risk and other messages, not strictly about risk, that express concerns, opinions, or reactions to risk messages

or to legal and institutional arrangements for risk management. (NRC, 1989, p 21)

Although risk communication should not be seen simply as a one-way form of persuasion (NRC, 1989; Fischhoff, 1989, 1995), in many cases risks are indeed communicated in a top-down fashion. When an institution, regulator, stakeholder or other body engages in risk communication, it is the responsibility of that body to communicate correctly and responsibly. In other words, according to the NRC 1989 definition, bodies communicating risks should design their strategies to assist the public in understanding the problem at hand. Fischhoff takes a similar view when he argues:

By definition, better risk communication should help its recipients to make better choices. It need not make the communicators' lives easier-recipients discover bona fide disagreements with the communicators and their institutions. What it should do is avoid conflicts due to misunderstanding, increasing the light-to-heat ratio in risk management, leading to fewer but better conflicts. (Fischhoff, 2007, p 31; also Fischhoff, 1995)

Examples of well-constructed risk communication strategies include Fischhoff and colleagues work at Carnegie Mellon University in developing communication leaflets for homeowners concerned about radon, to proactive strategies to assist girls to say no to teenage sex (Downs *et al.*, 2004a, b). Risk communication failures include the Swedish Food Administration's attempt to amplify a risk (acrylamide) that, in fact, should have been attenuated (Lofstedt, 2003), and Shell's mishandling of Greenpeace's occupation of its oil storage buoy Brent Spar – it supplied the worldwide media with great pictures of protestors being fired on by firehoses (Lofstedt and Renn, 1997). With regard to the aspartame case, the media communication strategy put forward by the Ramazzini Foundation did not assist public understanding of the problem at hand. Rather the many press conferences, press releases and interviews generated headlines such as “Fresh fears about aspartame” and “Is aspartame a sweet alternative or a health risk?” Had the Ramazzini scientists been interested in putting forward a responsible communication strategy, they would not have held press conferences on non-scientific peer-reviewed data, nor arranged press conferences to, in effect, give themselves research prizes. Many observers would call such strategies active media amplification or even scientific media manipulation (Friedman *et al.*, 1999), a topic that remains under researched (Kasperson *et al.*, 2003). Instead Ramazzini would have shared its findings with the wider peer community and put forward a communication notice on its website to the effect that there appeared to be a link between aspartame consumption and cancer, but that these findings had not been scientifically peer-reviewed.

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Table 1 How science results are communicated and disseminated (code of conduct)

<i>Good practices</i>	<i>Ramazzini</i>
Scientific peer-review journal	General media
Share data with regulators	Keep data secret
Dialogue with regulators	Little dialogue with regulators
Openness regarding funders	Secrecy regarding funders
Few if any press conferences	Many press conferences
Publish in best peer-review journals	Many non-peer-review journals
Proper risk communication	Faulty risk communication

Compared with a standard commercial best practice (such as GLP) facility, there were significant differences in the way the aspartame research findings at the Ramazzini Foundation were communicated (Table 1).

Recommendations

The Western world is presently awash with one food alarm or another (Lofstedt, 2006). As these food alarms seem to proliferate in numbers as well as in media attention, there is a need to develop proper science-communication strategies (Bostrom and Lofstedt, 2003; Lofstedt, 2003, 2006; McComas, 2006). When is a food scare real and when is it not? Are we dealing with real uncertainties or rather with manufactured ones? How does one best combat deliberate information vacuums?

With regard to the aspartame case, a number of issues arise including the following:

- the separation of science communication from public relations;
- the need for regulatory agencies and other stakeholders to understand the importance of risk communication;
- the need for establishing a science media communication check list.

These and related issues are discussed in this final section.

The need to separate science communication from public relations

This case study is an example of how scientists at the Ramazzini Foundation used the media to amplify their results concerning a controversial product. By holding five press conferences, conducting a lecture tour in Europe and North America and publishing multiple press releases, their research received international attention, causing unnecessary widespread public concern. The Ramazzini Foundation is obviously a well-honed public relations machine. The scientists there have an almost “natural” ability to interact with the media, and are able to put forward image-friendly poses (e.g. wearing lab coats and holding rats). However, is this responsible risk communication? Most

researchers would argue that such press conferences, press releases and related activities would be a job for a public relations firm.

Regulatory agencies and other stakeholders need to understand the importance of science/risk communication

Risk communication is never easy particularly with regard to cancer and food-related issues (Fischhoff, 1995, 1996, 1999; Kjaernes, 2006). Cancer is a term in today's society loaded with emotions and stigmatization (including death), and industry and regulators have been poor communicators regarding this disease (Fischhoff, 1999; Fischhoff *et al.*, 2002). Yet in this post-trust era it is important for the industry, politicians and regulatory agencies (particularly as the regulators that are no longer trusted outnumber those that are) to get this right and become better communicators (Lofstedt, 2005). If they do not properly address pseudo-scares based on non peer-reviewed science such as the Ramazzini findings, this type of study will proliferate still further. This is particularly the case for smaller regulatory agencies in the new member states where there is virtually no risk or science communication expertise.

The need to establish science media communication check list

The quality media communicates both good and bad science results. What is needed now for journalists and editors is to deal responsibly with risk-related issues and to be made aware of their role in socially amplifying risks. This is particularly crucial in a post-trust era, where scientific organizations, not following long developed academic norms with regard to sharing, publishing and disseminating science, are actively trying to promote the social amplification of risk. A check list developed in close collaboration between media, academics and other stakeholders may assist in helping journalists to differentiate different types of scientific findings (see e.g. Harrabin *et al.* (2003); for a critique see Horton, 2004).

Conclusions

This paper evaluated the communication and active social amplification of Ramazzini's research on aspartame. Based on the findings reported here, one can draw the following conclusions:

- Not all controversial science messages are passively amplified by the media. In some cases, research institutions actively pursue an aggressive media amplification strategy to help them guarantee media headlines. This is a research topic that has not been researched by the risk community to date.
- Academics, regulators and the media need to work together in developing responsible and credible risk communication strategies. This is particularly important in today's society considering the fact that we live in a post-trust era.

- Research organizations should in close collaboration work with policy makers to develop uniform scientific data disclosure guidelines similar to the US TSCA Section 8E.

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Conflict of interest: Professor Lofstedt is a member of Coca Cola Corporation's Science and Regulatory Affairs scientific advisory board.

Note

1 The *Daily Express* corrected themselves and apologized on 1 August 2006.

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